K112531

NOV 18 2011

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92.

Submitter: Vital Images, Inc.
5850 Opus Parkway
Suite 300
Minnetonka, MN 55343-4414

Contact Person: Daniel T. Biank
Regulatory Affairs Manager

Telephone: 952 – 487 – 9514

Fax: 952 – 487 – 9510

Email: dbiank@vitalimages.com

Date Prepared: August 30, 2011

Device Name

Trade Name: Vitrea® CT Myocardial Analysis
Common Name: Picture Archiving and Communications System
Classification Name: System, Image Processing, Radiological (21 C.F.R. 892.2050, LLZ)

Predicate Devices:

GE Medical Systems CardIQ Express Version 2.0 (K073138)
Siemens AG syngo.CT Cardiac Functions (K110366)

Device Description:

Vitrea® CT Myocardial Analysis is a post-processing software option for the Vitrea® software platform. It leverages existing Vitrea® functionality such as multiplanar reconstruction (MPR) images, maximum intensity projections (MIP), and volume rendering. Vitrea® CT Myocardial Analysis enables the visualization and analysis of the myocardium. It assists in analyzing the hyper/hypo dense areas of myocardial tissue. Its visualization tools include segmentation, color coding, and polar maps. Its analysis tools include measurements and comparison ratios. It also includes reporting tools for formatting findings and user selected areas of interest.

Intended Use:

Vitrea® CT Myocardial Analysis is an image analysis software application for cardiac Computer Tomography (CT) studies to visualize cardiovascular anatomy and pathology and to highlight and color code the presence of hypo/hyper dense areas of myocardial tissue.

Comparison with Predicate Devices:

The Vitrea® CT Myocardial Analysis application provides radiologists and cardiologists workflows similar to CardIQ Xpress 2.0 and syngo.CT Cardiac Function. These devices all include the ability to display two and three dimensional images of the cardiovascular anatomy generated from CTA exams of the heart. Vitrea® CT Myocardial Analysis is an option to enable a particular cardiac post-processing workflow for the myocardium. CardIQ Xpress 2.0 and syngo.CT Cardiac Function include the myocardium tool as part of a package of additional cardiac functions. Vitrea® CT Myocardial Analysis is substantially equivalent to the relevant CardIQ Xpress 2.0 and syngo.CT Cardiac Function tools.

Summary of Studies:

The software was designed, developed, and tested according to written procedures and applying risk management. Testing included verification, validation, and evaluating previously acquired diagnostic images. Software testing confirmed that the feature functions according to its requirements without impacting existing functionality. Validation found that users can operate the software and successfully perform the desired function. The software is designed to meet NEMA PS 3.1 - 3.18 Digital Imaging and Communications in Medicine (DICOM).

Testing supports a determination of substantial equivalence.

Conclusion:

Vitrea® CT Myocardial Analysis is substantially equivalent to the current cleared and marketed GE Medical Systems CardIQ Express Version 2.0 (K073138) and Siemens AG syngo.CT Cardiac Functions (K110366) based on the included studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Daniel Biank
Regulatory Affairs Manager
Vital Images, Inc.
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

MAR - 8 2012

Re: K112531
Trade/Device Name: Vitrea® CT Myocardial Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 30, 2011
Received: August 31, 2011

Dear Mr. Biank:

This letter corrects our substantially equivalent letter of November 18, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112531

Device Name: Vitrea® CT Myocardial Analysis

Indications for Use:

Vitrea® CT Myocardial Analysis is an image analysis software application for cardiac Computer Tomography (CT) studies to visualize cardiovascular anatomy and pathology and to highlight and color code the presence of hypo/hyper dense areas of myocardial tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112531